

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-03-1988
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Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
L May-09-84		MEETING REQUEST MTG 5/22: POSSIBILITY OF MULTIPLE-DOSE CLASSIFICAT'n		GRP	831426
L May-18-84		INITIAL SUBMISSION 166 VOLUMES. BREAST INDICATION		DRS	831482
		(a) TABLE OF CONTENTS vols 1.1 - 1.26; OPTIONAL EXPANDED SUMMARY			
		(b) LABEL # /PT 4 vol 1.26			
		(c) COMPONENTS & COMPOSITION # /PT 6,7 vol 1.26			
		(d) MANUF & CONTROLS vol 1.27-8			
		(e) PRECLINICAL # /PT 10 vols 1.29 - 1.39; RPT Nos. 1-159			
		(f) BIOPHARMACEUTIC PKG vols 1.40-44			
		(g) BIBLIOGRAPHY vols 1.45-48			
		(h) DRUG EXPER RPT vols 1.49-50			
		(i) CLINICAL STUDIES vols 1.51-2; PHARMACOKINETIC STUDIES			
		(j) CLINICAL STUDIES vols 1.53-77; DOSE TOLERANCE STUDIES			
		(k) CLINICAL STUDIES vol 1.78 - 1.150; CONTROLLED STUDIES			
		(l) CLINICAL STUDIES vols 1.151-155; OTHER CLINICAL STUDIES			
		(m) CLINICAL STUDIES vol 1.156; CLINICAL LAB STUDIES RELATED TO SAFETY			
		(n) CLINICAL STUDIES vols 1.157 - 1.166; SPECIAL PATIENTS			
L Oct-24-84		CORRESPONDENCE PATENT & EXCLUSIVITY INFO PER MCGINNIS' REQUEST, 10/23/84		ECM	831985
L Nov-12-84	L Oct-24-84	CORRESPONDENCE PATENT & EXCLUSIVITY INFO (CORRECTS 10/24/84 COMMUNICATION)		GWM	832039

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L Nov-28-84		CORRESPONDENCE	84-66	DJF	832068
		(a) SUMMARY, CLINICAL PROPOSED DRAFT SUMMARY BASIS OF APPROVAL			
L Jan-23-85		CORRESPONDENCE		DJF	850044
		AS REQUESTED BY CSO ALETA SINDELAR			
		(a) PUBLISHED RPTS METASTATIC BREAST CANCER (CANCER CLIN TRIALS 4:355-362, '81)			
L Apr-17-85		MEETING		DJF	850327
		AGENDA FOR 5/2/85 MTG re RESUBMN OF CLIN DATA FOR META BR CA			
L May-28-85	M May-02-85	CORRESPONDENCE		DJF	850508
		REVIEW OF LED's UNDERSTANDING OF THE 3/28 & 5/2/85 MEETINGS			
L Jul-12-85	L May-18-84	NOT APPROVABLE		DJF	850714
		LED MUST SUBMIT AMENDMENT CORRECTING DEFICIENCIES			
L Oct-21-85	F Jul-12-85	AMENDMENT		DJF	851114
		RESUBMISSION FOR BREAST INDICATION (INIT'L SUBM 5/18/84)			
F Nov-20-85	L Oct-21-85	CORRESPONDENCE		DJF	851157
		10/21/85 SUBM CONSIDERED MAJOR AMNDMT -NEW 180 DAY REVIEW PD			
L Nov-20-85	F Jul-12-85	AMENDMENT		DJF	860081
		RESPONSE TO 7/12 DEFIC LTR re MANUF/CTRLS NOT ADDRESSD 10/18			
		(a) LABEL-REVISED DRAFT, CONTAINER # 17312 TEXT CODE: PRD2 10ml VIAL			
		(b) LABEL-REVISED DRAFT, BOX # 17311 TEXT CODE: PRD2 10ml VIAL			

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
		(c) LABEL-REVISED DRAFT, CONTAINER # 17313 TEXT CODE: PRD2 15ml VIAL			
		(d) LABEL-REVISED DRAFT, BOX # 17314 TEXT CODE: PRD2 15ml VIAL			
		(e) LABEL-REVISED DRAFT, BOX # 17310 TEXT CODE: PRD2 12.5ml VIAL			
		(f) LABEL-REVISED DRAFT, BOX # 17309 TEXT CODE: PRD2 12.5ml VIAL			
		(g) LABEL-REVISED DRAFT, PKG INSERT # 17303 TEXT CODE: PRD4			
		(h) FORMULATION # /PT 7 COMPOSITION OF BOTH CLIN FORM'S I & II (PROP'D COMM'L FORM)			
		(i) CONTROLS # /PT 8(c) IN-PROCESS CTRLS--GOSPORT PRODUCTION (PER ITEM#2, 7/12 LTR)			
		(j) MONOGRAPH # /PT 8(d) SPECS FOR RAW MATERIAL & COMPONENTS			
		(k) AUTHORIZATION # /PT 8(n) HALDANE & WICKHAM LABS LTRS AUTH'g FDA TO X-REF THEIR DMFs			
		(l) STABILITY # /PT 8(p) SUMMARY & REPORTS			
		(m) ANALYSES REPORT OF ANALYTICAL FINDINGS FOR CL 232,315			
L Dec-06-85	L Oct-21-85	CORRESPONDENCE REPL PAGES (REPRESENTING CORRECTIONS) v2.41 pp 75-77, 87, 89		DJF	851175
L Jan-10-86		AMENDMENT		GRP	860021
		(a) MANUF & CONTROLS HEINRICH MACK NACHF. AMNDMT TO DMF#5203 FOR MANUFg MITO BULK			
L Jan-20-86	L Oct-21-85	CORRESPONDENCE		DJF	860032
		(a) CLINICAL STUDIES REANALYSIS OF DURATION OF RESPONSE DATA (NO SIGNIFICANT DIFF)			

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ		
L Jan-23-86		CORRESPONDENCE LIST OF INDIVIDUALS PARTICIPATING IN 3/6/86 ONCOL ADVIS MTNG	DJF	860066
L Jan-23-86		CORRESPONDENCE (a) SUMMARY, CLINICAL 20 COPIES FOR ADVISORY COMM REVIEW/MTG 3/6; NOT FILED IN NDA	DJF	860068
F Jan-27-86	L Nov-20-85	CORRESPONDENCE 11/20/85 AMNDMT DEEMED "MAJOR" --ADDL 2mo ADDED TO REVIEW PD	DJF	860074
L Jan-28-86		CORRESPONDENCE (a) CASE REPORT FORM LISTING OF CRF's (AS REQ'd BY TURNER) FROM 10/18/85 SUBM	DJF	860067
L Feb-05-86		TELEPHONE CALL MR. MEYER re FEASABILITY OF CYAN SPONSRSHP OF ADVIS COMM MTG	ECM	870059
F Feb-18-86	L Jan-10-86	CORRESPONDENCE 1/10/86 AMNDMT DEEMED "MAJOR" --REVIEW PD EXT 1 Mo.--7/23/86	GRP	860127
L Feb-25-86	L Oct-21-85	CORRESPONDENCE (a) SAFETY UPDATE - CLINICAL SAFETY UPDATE OF 10/21/85 RESUBMISSION	DJF	860146
L Feb-26-86	T Feb-13-86	CORRESPONDENCE RESPONSE TO BURKE'S ?? re CARDIOTOX RPT - v2.40, 10/21 RESUB	DJF	860152
B Mar-14-86		MEETING ADV COMM MTG (9-2 FAVOR NOVANT "ALTERNATIVE" TO ADRIA IN MBC	ECM	870060

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
L Mar-19-86	M Mar-14-86	CORRESPONDENCE GLOSSIES OF SLIDES USED IN LED PRES'n AT ADVIS COMMITTEE MTG		DJF	860226
L Mar-24-86	M Mar-14-86	CORRESPONDENCE MEMO TO SUTHERLAND: FOLLOW-UP REMARKS OF MTG(APPRVL TIMETBL)		ECM	870061
F May-30-86	L May-18-84	NOT APPROVABLE MANUF'g, STABILITY, LABELING, CLINICAL PHARM, PK DEFICIENCIES		DJF	860528
L Jun-09-86	F May-30-86	AMENDMENT RESPONSE TO MANUF'g & CONTROL DEFICIENCIES NOTED IN 5/30 LTR		GRP F	860538
		(a) MANUF & CONTROLS # 15201f(g) /PT 8h			
		(b) FORMULA & SOI # /PT 8b			
		(c) STABILITY REPORT # 86-494 /PT 8n 2mq/ml, UPDATE RPT			
L Jun-10-86	F May-30-86	CORRESPONDENCE AS REQ'd, 4 COPIES OF METHODS VALIDATION PACKAGE		GRP	860537
L Jul-16-86	F May-30-86	CORRESPONDENCE		DJF	860669
		(a) LABEL # 14545 TEXT CODE: PRD5 INSERT PROPOSED BY FDA w/ LEDERLE ALTERNATIVE WORDg/DELET'Ns			
L Aug-04-86		VALIDATION AS PER FDA CHEMIST (DR TOLGYESI) INSTRUCTIONS		GRP	860719

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
		(a) SAMPLES 1x5gm SAMPLES (CGBL & WG) & REFERENCE STNDS FOR VALIDATIONS			
L Aug-06-86		VALIDATION SAMPLES/REFERENCES STNDS TO BE USED FOR VALIDATION STUDIES		GRP	860756
F Aug-19-86	L Jul-16-86	CORRESPONDENCE 7/16/86 AMNDMT DEEMED "MAJOR"; ADDL 60 DAYS FOR REVIEW PD		GRP	860704
F Sep-08-86	L Jun-10-86	CORRESPONDENCE JUNE 9&10 AMDMTS "MAJOR" --2mo ADDED TO REVIEW PD: 8/10/86		DJF	860827
F Oct-07-86		NOT APPROVABLE		DJF	861059
L Oct-17-86		MEETING LED REQUESTS MTG re FURTHER REQRMTS FOR NDA APPROVAL		DJF	861033
L Nov-24-86	M Dec-18-86	MEETING PROPOSED AGENDA & LIST OF LED ATTENDEES FOR 12/18/86 MEETING		DJF	870718
L Dec-10-86	M Dec-18-86	MEETING BACKGROUND INFO FOR UPCOMING MTG, 12/18/86	86-40	DJF	870731
L Mar-12-87	L Jun-23-27	AMENDMENT DATA TAPES W/FULL RPTS OF REFORMATTED SUMMARY TABLES		DJF	870982
L Mar-12-87	L Dec-18-86	MEETING INTENT TO SUBMIT FULL RE-EVAL. & CLIN. SUMMARY OF 4-52		DJF	870981
		(a) CORRESPONDENCE INTENT TO SUBMT RE-EVAL. & CLIN SUMMARY OF STDY 4-52			

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ				
L Mar-19-87	F May-30-86	AMENDMENT 21 PRECLINICAL RPTS/9VOL INCLUDING FULL SUMMARIES FOR 3 STDs		DJF		870977
		(a) PRECLINICAL REPORT(s) REQUEST FROM FDA-TEL 6/23 & 8/27				
F Apr-23-87	Y Mar-12-87	* TELEPHONE CALL DR G BURKE, MRO		DJF	L	870291
		RE OUR 3/12/87 PROPOSAL FOR UPDATING 4-52, HE REQUESTED UPDATED SURVIVAL & CARDIOTOX DATA ALSO BE SUBMITTED FOR 3-48. THEY MIGHT ALSO BE INTERESTED IN SAME FOR 3-40. WILL CONFIRM IN OFFICIAL LETTER.				
F Apr-27-87	L Mar-19-87	ACKNOWLEDGEMENT SUBM NOT SUFFICIENT-NOT BEING PROCESSED AS AMENDMENT		DJF		870976
L May-05-87		# TELEPHONE CALL DR G BURKE, MRO		DJF		871452
		DR POSNER CALLED DR BURKE RE BREAST CANCER AMENDMENT AND PRE-NDA MTG ON LEUKEMIA. ALSO DISCUSSED THE POSSIBILITY OF A TREATMENT IND.				
F May-08-87	Y Mar-12-87	# TELEPHONE CALL DR KARL LINN, BIOMETRICS		DJF		870491
		HE INDICATED HE WAS HAVING A PROBLEM READING THE CARCINOGENECITY TAPES(SUBMITTED ON 3/12/87) INTO HIS COMPUTER. DR GOLDBERG TO CALL HIM BACK ON THE MATTER.				
F May-14-87		* TELEPHONE CALL DR. CARL LINN, BIOSTAT 5/8/87-TAPES SUBM. 3/12/87		DJF		870502
		REQUESTED INFO RE CARCINOGENECITY TAPES PROVIDED TO FDA ON 3/12/87. DR GOLDBERG PROVIDED CLARIFICATION INCLUDING ADDITIONAL TAPE SPECS.				

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
L May-15-87		CORRESPONDENCE INFO ON EFFECT OF NOV. IN LEUKEMIA IN PREP FOR PRE-NDA MEET		DJF	870636
L May-21-87		# MEETING DR G BURKE, MRO		DJF	871336
		OBTAINED ADVANCED COPY OF FDA LETTER REQUESTING ADDITIONAL DATA ON 3-40 & 3-48.			
F May-28-87		* TELEPHONE CALL MS A SINDELAR, CSO		DJF	870583
		PRE-NDA MTG TO DISCUSS LEUKEMIA FILING ARRANGED FOR JULY 7 AT 1:30PM IN 14B/45 AT FDA. DRS TEMPLE & BOTSTEIN + ONCOLOGY DIVISION STAFF WILL ATTEND.			
L Jun-29-87		MEETING PREP FOR PRE-NDA MTG. 7/7/87 - SENT TABLE OF CONTENTS	87-14	DJF	870969
		(a) CORRESPONDENCE SENT TABLE OF CONTENTS FOR LEUKEMIA FILING			
L Jul-07-87		# MEETING DR. TEMPLE AND ONCOLOGY DIVISION MEMBERS		DJF	870789
L Jul-21-87		CORRESPONDENCE MINUTES OF PRE-NDA MTG W/FDA 7/7/87		DJF	871322
L Jul-21-87		* TELEPHONE CALL DR R TEMPLE, DIRECTOR		DJF	871002
		DR CARTWRIGHT SPOKE WITH DR TEMPLE FOLLOWING UP OUR MTG OF 7/7/87. TEMPLE POSITIVE ABOUT THE LEUKEMIA CLAIM AND ANXIOUS TO RECEIVE DATA ON BREAST & LEUKEMIA ASAP AS THE NEXT ADVISORY MTG IS SCHEDULED FOR EARLY DECEMBER.			

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L Jul-23-87		MEETING DR D HERSEY, SEC ONCOL ADV COMMITTEE		DJF	870911
		NEXT ADVISORY COMMITTEE TENTATIVELY SCHEDULED FOR DECEMBER 7-8, 1987.			
L Jul-28-87		DRUG EXPERIENCE RPT SAFETY EVENT REPORT-NETHERLANDS #3062	87-17	DJF	870961
		(a) SAFETY UPDATE DEAF & BLIND AFTER TREAMNT-DIED FEW DAYS LATER PAT.#3062			
L Jul-29-87		CORRESPONDENCE LETTER OF AUTHORIZATION FOR SPEITZER	87-18	DJF	870960
		(a) AUTHORIZATION STDYING ETOPOSIDE&THIO.W/AUTOLOGOUS MARROW SUPPT/BREST CANCR			
L Aug-17-87		* AMENDMENT RAW DATA FOR UPDATES ON 4-52, 3-40, & 3-48		DJF	871091
		(a) CASE REPORT FORM FDA REQUESTS:5/30/86;10/6/86;5/10,1987:PROT 4-52,3-40,3-48 RAW DATA SUBMITTED FOR BREAST STUDIES 4-52, 3-40, & 3-48			
L Aug-26-87		TELEPHONE CALL DR D HERSEY, SEC ONCOL DRUGS ADV COMM		DJF	871335
		LATEST LIST OF PANEL MEMBERS FROM ADVISORY PANEL REC'D.MTG TENTATIVELY SCHEDULED FOR 12/7&8.			
L Sep-09-87		CORRESPONDENCE RE-REQUEST FOR GOSPORT INSPECTION AFTER 1ST REQ. CANCELLED		GRP	871391
L Sep-11-87		* TELEPHONE CALL DR J JOHNSON, GR DIRECTOR ONCOLOGY		DJF	871111

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DR JOHNSON RECEPTIVE TO PIECEMEAL SUBMISSION OF
LEUKEMIA CLAIM. WOULD DO HIS BEST TO REVIEW BEFORE
ADVISORY MTG IN DECEMBER.

F Sep-15-87		* TELEPHONE CALL DR G BURKE, MRO		DJF	871117
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REQUESTED CRFS FOR 4-52 RESPONDERS WHOSE RAW DATA
WERE NOT INCLUDED IN 8/87 FILING.

L Sep-16-87		* TELEPHONE CALL DR J JOHNSON, ONCOLOGY GROUP DIRECTOR		DJF	871128
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DISCUSSED SCHEDULE FOR PIECEMEAL FILING OF
LEUKEMIA CLAIM & CONTENT OF PACKAGE FOR ADVISORY
COMMITTEE IN DECEMBER.

L Sep-16-87		CORRESPONDENCE LIST OF SUBMISSIONS FOR NEXT MONTH FOR BREAST & LEUKEMIA		DJF	871230
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L Sep-16-87		CORRESPONDENCE LIST OF RESPONDERS IN THE 4-52 STUDY OF NOV. IN BREAST CANCER		DJF	871229
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(a) CORRESPONDENCE
LIST OF RESPONDERS IN 4-52 STUDY OF NOV. IN BREAST
CANCER.

L Sep-18-87	L Sep-11-87	TELEPHONE CALL		DJF	871199
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NOTIFIED DR. JOHNSON ABOUT PIECEMEAL SUBM. OF COMP
FOR LEUKEMIA & BREAST WHICH WILL HOPEFULLY ALLOW
INCLUSION OF BOTH CLAIMS ON AGENDA FOR ADV. COMM
MTG.

L Sep-21-87		* AMENDMENT CASE RECORDS FOR 3-74 & 3-603 LEUKEMIA TRIALS		DJF	871228
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(a) CLINICAL STUDIES
TRETMT OF ADLT ACUTE NON-LYMPH LEUKEMIA/OD
GRANTED 7/13/87

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CRF'S FOR 3-74 AND 3-603 FILED TO FDA AS PART OF
APRECLINICAL SUBMISSION FOR A CLAIM IN ANLL.
ADDITIONAL SUBMISSIONS PROJECTED FOR SEPTEMBER 30
AND OCTOBER 15.

L Sep-22-87

TELEPHONE CALL DJF 871130
DR D HERSEY, SEC ONCOL DRUGS ADV COM

DR ALBERT BERNARTH ADDED TO ONCOLOGIC DRUGS
ADVISORY PANEL. NO OFFICIAL AGENDA ITEMS
IDENTIFIED.

L Sep-30-87 F

* AMENDMENT DJF 871198
5/30/86, 10/7/86, 5/20/87, MTGS: 12/18/86 & 7/7/87

- (a) CORRESPONDENCE
RESPONSE TO PHARMACOK. QUESTIONS FROM FDA LETTER
5/30/86
- (b) SUMMARY, CLINICAL
UPDATED 4-52 SUMM./SURV. CURVES
3-40 & 3-48/CLIN. PHARM. SUMM.

UPDATE OF 4-52, 3-40 AND 3-48 + RESPONSE TO PK
QUESTIONS-REPRESENTS A FULL RESPONSE TO FDA
LETTERS 5/30/86, 10/7/86 AND 5/20/87.

L Oct-01-87

* CORRESPONDENCE DJF 871161
DR CARTWRIGHT'S COMMENTS TO DR TEMPLE RE BR & LEUK
SUBMISS.

DR CARTWRIGHT INFORMS DR TEMPLE VIA LETTER ABOUT
OUR PLANS FOR PIECEMEAL FILINGS FOR THE BREAST AND
LEUKEMIA CLAIMS.

L Oct-02-87

* AMENDMENT DJF 871197
CLINICAL DATA TO SUPP. ADULT ACUTE NON-LYMPHOCYTIC
LEUKEMIA

- (a) CLINICAL REPORT(s) # /PT b
MULTI-CTR STDY 3-74+ARA-CVS. CERUBIDINE+ARA-C/11
SUPP. STUDIES
- (b) BIBLIOGRAPHY
+REPRINTS ITEM#8 REPRES. COMBINED CLIN & STAT
PRESENTATION

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NDA AMENDMENT INCLUDING CLINICAL REPORTS OF 3-74 & 11 SUPPORTIVE TRIALS + A CLINICAL BIB SUBMITTED TO FDA.

L Oct-09-87 # TELEPHONE CALL DJF 871196

OCT 8 SPOKE W/DR. HERSEY ABOUT PREP FOR ADVISORY COMM. IN DEC. HE NOTED BOTH LEUK. & BREAST CLAIMS FOR NOV. WERE TENTATIVELY ON AGENDA. LEUK-MORNING OF DEC.7 W/ BREAST IN AFTERNOON. CONTINGENT UPON FDA REVIEWING PKGS. SUBM. & ONES TO BE FILED.HE ADDED THAT CRITERIA FOR APPROV. OF A SOLID TUMOR TYPE (OVARIAN CANCER) MIGHT BE AN AGENDA ITEM.NEEDTO C/B IN A COUPLE WEEKS FOR MORE INFO.

F Oct-16-87 VALIDATION GRP 880066
VALIDATION TESTING COMPLETE & SUITABLE
W/MODIFICATIONS

F Oct-16-87 # VALIDATION GRP 880036
METHODS VALIDATION APPROVED WITH SOME
MODIFICATIONS

F Oct-16-87 # TELEPHONE CALL DJF 871265
DR G BURKE, MRO

SPOKE WITH DR MARCUS RE CASES OF
HYPERBILIRUBINEMIA IN 3-74 LEUKEMIC PATIENTS AND
CODING/TRANSCRIPTION ERRORS IN DOCUMENTING ADR'S.

L Oct-19-87 * CORRESPONDENCE DJF 871321
PROPOSED LABELNG-REQUESTED BY A.SINDELAR
10/16/87-BREAST

PROPOSED BREAST LABELING FORWARDED TO FDA.

F Oct-20-87 ACKNOWLEDGEMENT DJF 871419
BR CA DEFICIENCIES:ITEMS 6 (PHARMACO) & 8 (CLIN &
STAT)

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L Oct-21-87	L Mar-12-87	CORRESPONDENCE REPLCMNT TAPE-NB8238 RAT CARCINOGEN. STDY #81152		DJF	871320
L Oct-22-87		* CORRESPONDENCE DOCUMENTATION FOR ADVISORY COMM FOR DECEMBER MTC (a) LABEL-DRAFT, PACKAGE INSERT COVERNG USE IN BOTH LEUKEMIA & BREAST CANCER (b) CLINICAL REPORT(S) MULTICENTER STUDIES: 3-603, NOV + ARA-C VS CERUBIDINE+ARA-C FINAL INSTALLMENT OF CLINICAL DATA TO SUPPORT THE LEUKEMIA (ANLL) CLAIM FILED AT FDA. SUBMISSION INCLUDES 3-603 CLINICAL REPORT, INTEGRATED SUMMARIES OF SAFETY & EFFICACY AND PROPOSED LABELING COVERING BOTH THE LEUKEMIA & BREAST CA CLAIMS.		DJF	871319
F Oct-28-87		* TELEPHONE CALL DR G BURKE, MRO PHONED DR S MARCUS REQUESTING INFORMATION ON LEUKEMIA STUDY 3-603 RELATED TO MISSING BONE MARROW DATA & PROBLEMS IN THE PACIFIC REGION.		DJF	871328
F Oct-29-87		# TELEPHONE CALL DR R STEIN, FDA BIOSTATISTICIAN PHONED DR J GOLDBERG RE QUESTIONS ON THE 4-52 BREAST CA REPORT RELATED TO 80 CUTOFF VALUE FOR SGOT & ESTIMATION OF TTD.		DJF	871348
F Oct-30-87		* TELEPHONE CALL DR G BURKE, MRO CALLED DR S MARCUS RE HIS RECENT REQUEST FOR THE MISSING BONE MARROW RATING DATA.		DJF	871337
L Nov-02-87		# RESPONSE TO FDA REPLAC OF APP VI TO 3-603 STUDY REQ BY DR BURKE 10/28/87		DJF	871445

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
		REPLACEMENT OF APP VI OF THE 3-603 STUDY SUBMITTED ON 10/22/87 FILED PER DR BURKE'S REQUEST OF 10/28/87			
L Nov-04-87		CORRESPONDENCE HANDOUTS FOR 12/7-8/87 ONCOLOG ADV COMM MTG (20 CC)	DJF		871413
L Nov-06-87		CORRESPONDENCE REPLACEMENT COPY:APPEND#6 SUB.11/2/87;APPEND#14 SUB.10/22/87	DJF		871417
F Nov-06-87		# TELEPHONE CALL DR D HERSEY, SEC ONCOL DRUGS ADV COMM	DJF		871376
		QUESTIONS FROM ONCOLOGY DIV TO ADVISORY PANEL OBTAINED.			
L Nov-12-87		PERIODIC REPORT 10/1/86 - 9/30/87	AH		880091
L Nov-12-87		# RESPONSE TO FDA LISTING OF LAB CONVERSION FACTORS FILED	DJF		871446
		A LISTING OF LAB CONVERSION FACTORS FOR THE 3-603 STUDY FILED PER DR BURKE'S REQUEST.			
F Nov-13-87		* TELEPHONE CALL DR G BURKE, MRO	DJF		871395
		REQUESTED ADD'L ANALYSES OF SURVIVAL,RR & RESPONSE DURATION FOR INTENT-TO-TREAT PTS(EXCEPT THOSE WRONGLY DIAGNOSED) IN 3-74 & 3-603. ALSO TO RUN SAME DELETING HONG KONG & TAIWAN.			
L Nov-19-87		# TELEPHONE CALL DR G BURKE, MRO	DJF		871431

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			

DR S MARCUS PHONED RE ERRATA IN THE 3-603 LEUKEMIA STUDY.

F Nov-19-87 # TELEPHONE CALL DJF 871451
DR R STEIN, BIOSTATISTICIAN

REQUESTED FROM MR WEISS CALCULATION OF CONFIDENCE LIMITS FROM THE LEUKEMIA STUDIES 3-74 & 3-603.

F Nov-24-87 # TELEPHONE CALL DJF 871439
DR G TURNER, OFFICE OF SCIENTIFIC INVEST

REQUESTED 3 VOLUMES FROM 10/2/87 LEUKEMIA SUBMISSION CONTAINING CLINICAL REPORT OF 3-74 STUDY TO AID IN HIS SELECTION OF SITES TO AUDIT

L Nov-24-87 # CORRESPONDENCE DJF 871448
3-40(BREAST) SUBGROUP ANALYS BASED ON PROG FACTORS

AN ANALYSIS OF SURVIVAL DATA FROM THE 3-40 BREAST STUDY WAS SUBMITTED FOR SUBGROUPS BASED ON PROGNOSTIC FACTORS(AS WAS DONE FOR YHE 4-52 STUDY).

L Nov-24-87 # RESPONSE TO FDA DJF 871447
ADD'N SUBSET ANALYS 3-74/3-603 & EVAL OF SUPP CARE 3-603

ADD'N SUBSET ANALYSES FOR RESPONSE RATE, SURVIVAL, & RESPONSE DURATION FILED PER DR BURKE,S REQUEST. ALSO AN EVALUATION OF THE QUALITY OF SUPPORTIVE CARE FOR PATIENTS WITH INFECTIONS IN 3-603 WAS PROVIDED.

F Nov-25-87 # TELEPHONE CALL DJF 871437
DR G BURKE, MRO & DR J JOHNSON, GR DIR ONCOL

ASKED THAT WE RESTRICT OUR PRESENTATIONS ON LEUKEMIA & BREAST CANCER TO 45 MIN EACH.

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19-297 NDA NOVANTRONE *MITOXANTRONE INJ

L Nov-30-87		RESPONSE TO FDA COPIES OF 3-74 VOLS(LEUK) TO DR G TURNER AS REQUESTED		DJF	871440
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(a) CORRESPONDENCE
FDA REQ FOR VOL 1,2,3(14.1,14.2,14.3)LEUKEMIA 3-74
STUDY

L Nov-30-87		# TELEPHONE CALL DR G BURKE, MRO		DJF	871449
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REQUESTED SUPPORTIVE CARE INFO ON PATIENTS WHO
DIED DURING CONSOLIDATION THERAPY IN THE 3-74 &
3-603 LEUKEMIA STUDIES. ALSO WANTED HAZARD RATIOS
FOR THE 3-603 SUBSET ANALYSES PROVIDED 11/24/87.
ASKED THAT WE OFFICIALLY SUBMIT THE BREAST CA
SUMMARY SENT TO THE ADVISORY PANEL TO THE NDA.

L Dec-01-87		CORRESPONDENCE LIST OF LEDERLE PRESENTERS(NOVANTRONE)@ FDA ADV COMM MTG		DJF	871490
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L Dec-01-87		# TELEPHONE CALL DR D HERSEY, SEC ONCOL DRUGS ADV COMM		DJF	871453
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DR DEAN BRENNER OF ROSWELL PARK WILL BE THE NEWEST
MEMBER OF THE ADVISORY PANEL.

L Dec-02-87		# TELEPHONE CALL DR G BURKE, MRO		DJF	871454
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DR S MARCUS CALLED ABOUT THE PRESENTATION OF
SUPPORTIVE CARE DATA FOR PATIENTS IN THE 3-603
LEUKEMIA STUDY.

L Dec-03-87		# TELEPHONE CALL DR G BURKE, MRO		DJF	871462
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PROVIDED DR BURKE WITH SURVIVAL HAZARD RATIOS ON
SUBGROUPS OF PATIENTS FROM THE 3-603 LEUKEMIA
STUDY REQUESTED ON 11/30/87.

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
L Dec-07-87		* MEETING ONCOLOGIC DRUGS ADVISORY COMM MTG LEUKEMIA APPROVED		DJF	871524
		ONCOLOGIC DRUGS ADVISORY COMMITTEE MEETING - NOVANTRONE APPROVED 7-2(2 ABSTAINING) FOR FIRST-LINE USE IN COMBO VS ANLL. 11-0 VOTE AGAINST ITS USE AS SINGLE USE IN RELAPSED ANLL. USE IN BREAST CANCER NOT APPROVED BY AN 8-3 VOTE.			
F Dec-08-87		# MEETING DR G TURNER, OFFICE OF SCIENTIFIC INVESTIGATION		DJF	871508
L Dec-09-87		* RESPONSE TO FDA		DJF	871520
		(a) CASE REPORT FORM RANDOM CRFs FROM #3-74 REQ BY DR G TURNER(FDA)FOR AUDITING		/003-074-0	
F Dec-09-87		# TELEPHONE CALL DR G BURKE, MRO		DJF	871527
		CALLED DR MARCUS RE WORDING OF THE PI RELATED TO THE CONSOLIDATION PHASE OF TREATMENT AND LISTING OF ADRS FOR THE INDUCTION PHASE IN STUDY 3-74.			
L Dec-10-87	F Oct-15-87	RESPONSE TO FDA WE AGREE TO REQUESTED MODIFICATIONS TO ANALYTICAL TESTING		GRP	880030
L Dec-10-87		* RESPONSE TO FDA DRAFT LABELING FOR USE IN LEUKEMIA		DJF	871521
		(a) LABEL,DRAFT,PACKAGE INSERT PROP.DRAFTLABEL FOR ANLL + ADV REAC LIST(3=74/3-603)DR.BURKE			
		DRAFT LABELING FOR USE IN ANLL REFLECTING SEVERAL CONVERSATIONS WITH DR G BURKE WERE SUBMITTED TO FDA ALONG WITH A WANG DISKETTE.			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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19-297 NDA NOVANTRONE *MITOXANTRONE INJ

L Dec-10-87	F Oct-16-87	# CORRESPONDENCE WE AGREE TO SUGGESTED ANALYTICAL MODIFICATIONS		GRP	880013
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F Dec-11-87		# TELEPHONE CALL DR G BURKE, MRO		DJF	871528
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CALLED DRS MARCUS AND FOLEY SEVERAL TIMES RE THE FINAL LABELING FOR USE IN ANLL. FDA HAS MADE A NUMBER OF REVISIONS TO OUR PROPOSED TEXT SUBMITTED EARLIER IN THE DAY EG THE PK SECTION AND THAT DEALING WITH CARDIOTOXICITY.

F Dec-14-87		* MEETING DR G BURKE, MRO & MS A SINDELAR, CSO		DJF	871539
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DRS CARTWRIGHT & SALETAN WERE ASKED TO STOP OFF AT THE ONCOLOGY DIV TO DISCUSS REVISIONS TO OUR PROPOSED PI SUBMITTED ON 12/11/87. AGREEMENT WAS REACHED ON REVISIONS.

F Dec-15-87		* TELEPHONE CALL MS A SINDELAR, CSO		DJF	871540
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CALLED TO INDICATE TWO ADDITIONAL CHANGES TO PI RE SINGLE DOSE USE AND CHANGE OF LABEL FROM "FOR INJECTION" TO "INJECTION". WE EXPRESSED OUR OBJECTIONS TO THE LATTER REVISION FROM A SAFETY VIEWPOINT.

F Dec-23-87		* APPROVAL APPROVAL FOR INITIAL RX OF ANLL IN COMBINATION		DJF	880009
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L Dec-30-87		# TELEPHONE CALL MR K FEATHER, DIR DIV DRUG ADVERTISING		NAS	880007
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APPROVED TRADEMARK NOVANTRONE MITOXANTRONE HCL FOR PRE-LAUNCH REMINDER AD.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
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19-297 NDA NOVANTRONE *MITOXANTRONE INJ

L Jan-04-88		# TELEPHONE CALL MS A SINDELAR, CSO		DJF	880008
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REVISED ADR TABLE AGREED TO FOR FINAL PRINTED
LABELING.

F Jan-12-88	L Jan-05-88	* ACKNOWLEDGEMENT FDA ACKNOWLEDGES RECEIPT OF SUPP 1/12/88	S001	GRP	880132
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L Jan-20-88	L Dec-20-87	* SUPPLEMENT SUBMISSION OF PRESERVATIVE EFFICACY FOR MULTIPLE DOSE VIAL		GRP	880135
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